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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,796	DENNY ET AL.	
	Examiner	Art Unit	
	/Venkataraman Balasubramanian/	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27,28,30-33 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *27 and 36* is/are allowed.

6)☒ Claim(s) *28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, which included cancellation of claims 1-26,29, 34, 35 and amendment to claims 27, 28 and 30-33 along with a an affidavit from William Wilson, filed on 12 /22/2009, is made of record. Claims 27, 28 and 30-33 are now pending. In view of applicants' response, all 112 second paragraph rejections and prior art 102 and 103 rejections made in the previous office action have been obviated. However, the following 112 first paragraph scope of enablement rejection made in the previous office action is applied to currently pending method of use claims.

Information Disclosure Statement

References cited in the Information Disclosure Statement, filed on 12/22/2009, are made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28 and 30-33 are rejected under U.S.C. 112, first paragraph, because the specification while being enabling for treating cervical carcinoma, colon carcinoma and non-small cell lung cancer with compound of claim 27 in conjunction with radiation therapy, does not reasonably provide enablement for treating any or all cancers and solid tumors as generically embraced in the instant claims. The specification does not enable any physician skilled in the art of medicine, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) level of skill in the art, 8) the quantity of experimentation needed.

1) The nature of the invention:

The instant method of use claim 28 drawn to therapy for cancers with various 1,2,4-benzotriaizne-1,4-oxides, claims 30-31 and 33 are drawn to radiation therapy and radiosensitizing of solid tumor in presence of the1,2,4-benzotriaizne-1,4-oxide of claim 27.

Instant claims, as recited, are reach through claims. A reach through claim is a claim drawn to a mechanistic, receptor binding or enzymatic functionality in general format and thereby reach through a scope of invention for which they lack adequate written description and enabling disclosure in the specification.

In the instant case, based on the inhibition of cell proliferation by cytotoxicity via hypoxia, by the instant compounds, instant claims reach through inhibiting and treating any or all cancers and tumors in general and thereby they lack adequate written description and enabling disclosure in the specification.

Cancer is just an umbrella term. Tumors vary from those so benign that they are never treated to those so virulent that all present therapy is useless. Accordingly,

treatments for cancer are normally tailored to the particular type of cancer present, as there is no, and there can be no “magic bullet” against cancer generally.

Thus, the scope of claim is extremely broad.

More specifically, in the instant case, based on the mode of action of instant compounds as inhibitor of cell proliferation by imparting cytotoxicity using hypoxia of tumor cells, based on limited assay, it is claimed that treating any or all solid tumors or cancers in general, for which there is no enabling disclosure. The scope of the claims includes any or all cancer based on the mode of action of the compound of instant claims for which there are no enabling disclosure. In addition, the scope of these claims as recited would include treatment of various cancers such as lung cancer, bone cancer, pancreatic cancer, skin cancer. cancer of the head or neck, cutaneous or intraocular melanoma, uterine cancer, ovarian cancer, rectal cancer, cancer of the anal region. stomach cancer, colon cancer, breast cancer, uterine cancer, carcinoma of the fallopian tubes, carcinoma of the endometrium, carcinoma of the cervix, carcinoma of the vagina, carcinoma of the vulva, Hodgkin's disease, cancer of the esophagus, cancer of the small intestine, cancer of the endocrine system, cancer of the thyroid gland, cancer of the parathyroid gland, cancer of the adrenal gland, sarcoma of soft tissue, cancer of the urethra, cancer of the penis, prostate cancer, chronic or acute leukemia, lymphocytic lymphomas, cancer of the bladder, cancer of the kidney or ureter, renal cell carcinoma, carcinoma of the renal pelvis, neoplasms of the central nervous system (CNS), primary CNS lymphoma, spinal axis tumors, brain stem glioma, pituitary adenoma, or a

combination of one or more of the foregoing cancers, which is not adequately enabled solely based on the activity of the compounds provided in the specification.

Moreover many if not most of diseases such as, lung cancer, brain cancer, pancreatic cancer, colon cancer etc. are very difficult to treat and despite the fact that there are many anticancer drugs.

The instant compound is disclosed to have cell proliferation inhibitory activity by imparting cytotoxicity via hypoxia and it is recited that the instant compounds are therefore useful in treating any or all cancers and solid tumors stated above for which applicants provide no competent evidence. It appears that the applicants are asserting that the embraced compounds because of their mode action as cell proliferation inhibitor that would be useful for all sorts of cancers. However, the applicants have not provided any competent evidence that the instantly disclosed tests are highly predictive for all the uses disclosed and embraced by the claim language for the intended host.

The scope of the invention includes the thousands cancers embraced as stated above.

No compound has ever been found to treat cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a “compound” is contrary to our present understanding of oncology. Cecil Textbook of Medicine states, “each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study” (see the enclosed article, page 1004). Different

types of cancers affect different organs and have different methods of growth and harm to the body.

Also see the PTO website

<<http ://www.uspto.gov/web/offices/pac/dapp/1pecba.htm#7>>

ENABLEMENT DECISION TREE, Example F, situation 1) which is directed to the scope of cancer.

Also, note MPEP 2164.08(b) which states that claims that read on "... significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative.". Clearly that is the case here.

Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally. Note substantiation of utility and its scope is required when utility is “speculative”, “sufficiently unusual” or not provided. See Ex parte Jovanovics, 211 USPQ 907, 909; In re Langer 183 USPQ 288. Also note Hoffman v. Klaus 9 USPQ 2d 1657 and Ex parte Powers 220 USPQ 925 regarding type of testing needed to support in vivo uses.

Next, applicant's attention is drawn to the Revised Utility and Written Description Guidelines, at 66 FR 1092-1099, 2001 wherein it is emphasized that 'a claimed invention must have a specific and substantial utility'. The disclosure in the instant case is not sufficient to enable the instantly claimed method treating solely based on the inhibitory activity disclosed for the compound.

2) The state of the prior art: The state of the art is indicative of the requirement for undue experimentation. See Bussink et al., Radiotherapy and Oncology, 67, 3-15, 2003. Especially see concluding paragraph. Hence, in the absence of showing of correlation between all the cancers claimed as capable of treatment with instant compound with or without radiation therapy, one of skill in the art is unable to fully predict possible results from the administration of the compounds of formula (I) due to the unpredictability of the role of the instantly claimed compounds. For example, since it is known that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, that cancer classification has been based primarily on morphological appearance of the tumor and that tumor with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy.

Applicant's disclosure does not enable one of ordinary skill in the art to use the claimed invention within the entire scope of the diseases listed above. There is no compound, let alone an entire class of compounds that can treat the various and divergent cancers listed above, as claimed. Cell proliferation by various mode of action is still exploratory and requires further experimentation.

Those of skill in the art recognize that in vitro assays and or cell-cultured based assays are generally useful to observe basic physiological and cellular phenomenon such as screening the effects of potential drugs. However, clinical correlations are generally lacking. The greatly increased complexity of the in vivo environment as compared to the very narrowly defined and controlled conditions of an in- vitro assay does not permit a

single extrapolation of in vitro assays to human diagnostic efficacy with any reasonable degree of predictability. In vitro assays cannot easily assess cell-cell interactions that may be important in a particular pathological state. Furthermore it is well known in the art that cultured cells, over a period time, lose phenotypic characteristics associated with their normal counterpart cell type. Freshney. (Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, p4) teach that it is recognized in the art that there are many differences between cultured cells and their counterparts in vivo. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation in vivo. Without this control, cellular metabolism may be more constant in vitro but may not be truly representative of the tissue from which the cells were derived. This has often led to tissue culture being regarded in a rather skeptical light (p. 4, see Major Differences/n Vitro). Further, although drawn specifically to cancer cells, Dermer (Bio/Technology, 1994, 12:320) teaches that, "petri dish cancer" is a poor representation of malignancy, with characteristics profoundly different from the human disease Further, Dermer teaches that when a normal or malignant body cell adapts to immortal life in culture, it takes an evolutionary type step that enables the new line to thrive in its artificial environment. This step transforms a cell from one that is stable and differentiated to one that is not. Yet normal or malignant cells in vivo are not like that. The reference states that evidence of the contradictions between life on the bottom of a

lab dish and in the body has been in the scientific literature for more than 30 years. Clearly it is well known in the art that cells in culture exhibit characteristics different from those in vivo and cannot duplicate the complex conditions of the in vivo environment involved in host-tumor and cell-cell interactions.

Applicants claim the treatment of various cancers. The state of the prior art is that cancer therapy remains highly unpredictable. The various types of cancer have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, that cancer classification has been based primarily on morphological appearance of the tumor and that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al., page 531). Furthermore, it is known that chemotherapy is most effective against tumors with rapidly dividing cells and that cells of solid tumors divide relatively slowly and chemotherapy is often less effective against them. It is also known in the prior art that the role of hypoxia in tumor biology remains incompletely understood and inhibition of tumor cell proliferation by hypoxia of is still exploratory. It clear that there are different cellular mechanisms, the unpredictability in the art and the different treatment protocols.

3) The predictability or lack thereof in the art: Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating any or all condition of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological

activity such as the instant case, “the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved”. See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

4) The amount of direction or guidance present:

A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds which fall within the scope of a claim will posses the alleged activity. The only direction or guidance present in the specification is the listing of cancers applicant considers treatable. Biological activity is generally unpredictable and a highly structure specific area, and the data provided is insufficient for one of ordinary skill in the art to extrapolate to the other compounds of the claims.

The disclosure does not provide how this in vitro data correlates to the treatment of the assorted diseases claimed. The instant specification is short of any examples or data in regards to the supposed treating of the aforementioned cancers. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

5) the presence or absence of working examples: Specification has no working examples to show treating all cancers including all solid tumors and the state of the art

is that the effects of cell proliferation inhibitors such bioreductive agents are unpredictable.

6) The breadth of the claims: The instant claims embrace treatment of any or all solid tumors or cancers. For such a scope, there is no enabling disclosure in the specification.

7)The level of skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of the instant claims for the treatment of the various claimed cancers as a result necessitating one of skill to perform an exhaustive search for which disorders can be treated by what compounds of the instant claims in order to practice the claimed invention.

8) The quantity of experimentation: The quantity of experimentation needed is undue experimentation. It would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the pharmaceutical use, for the reasons stated above. One of skill in the art would need to determine what cancers out of the multitude claimed would be benefited (i.e. treated) by the administration of the compounds of formula (I) and would furthermore have to

determine which of the claimed compounds would provide treatment of which cancer or solid tumor.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of enzyme-inhibitor interactions in general, and the lack of working examples regarding the activity of the claimed compounds towards treating the variety of cancers of the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compounds encompassed in the instant claims, with no assurance of success.

MPEP §2164.01(a) states, “A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was 'filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright,

999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

This rejection is same as made in the previous office action but now limited to scope of claims 28 and 30-33 and is modified based on the results shown in the affidavit of William Wilson. In addition, passage, objected by Applicants, pertaining to hypoxia inducing factor and alerted kinase activity is deleted. All cancers specifically tested are deemed as enabled and general enablement for all cancers generically claimed are not deemed as enabled. Applicants' traversal is not persuasive.

First of all, as stated above, instant claims, as recited, are reach through claims. A reach through claim is a claim drawn to a mechanistic, receptor binding or enzymatic functionality in general format and thereby reach through a scope of invention for which they lack adequate written description and enabling disclosure in the specification. In the instant case, based on the inhibition of cell proliferation by cytotoxicity as bioreductive drug using hypoxia by the instant compound, instant claims reach through inhibiting and treating any or all cancers and tumors in general and thereby they lack adequate written description and enabling disclosure in the specification.

Applicants have argued that by presenting an affidavit that the method of use claims as recited are enabled. However, careful analysis of the affidavit would show that the results are limited to treating specific cancers with instant compound and radiation. There is no showing that all tumors behave in the same and the compound would kill such tumor cells upon radiosenzititation . In addition, there is no showing even with the

selected cell lines that the specific compound of claim 27 alone without radiation is effective. Hence, enablement for treating all cancers and solid tumors with the compound by itself is lacking.

Furthermore, instant specification clearly shows that structurally related TPZ which shares same mode of action as bioreductive drug and radiosensitizing agent is not effective for treating all tumors. See pages 2-4, especially page 4 for drawbacks of TPZ. In fact TPZ or TPZ analogs have not yet found treat all cancers. Applicants have not shown that instant compound has superior activity by a comparison. The assay in specification and the experiment in affidavit are rather limited. In an unpredictable art, such as cancer therapy, in vitro assays may be used for enablement only if there is a well-established correlation between the assay and clinical efficacy. Several case laws lend support for the basis of this rejection.

The issue in Ex parte Balzarini 21 USPQ2d 1892 concerned HIV treatment and the Board of Patent Appeals and Interferences wrote "While the in vitro testing performed on these anti-viral compounds appears to be useful as a screening tool in order to determine which of these anti-viral compounds are candidates for further testing to determine if they possess in vivo utility, the in vitro tests were not predictive of in vivo efficacy."

The issue in Fujikawa v. Wattanasin 39 USPQ2d 1895 was adequacy of in vitro testing of inhibitors of cholesterol biosynthesis and U.S. Court of Appeals Federal Circuit wrote, "in vitro results, in combination with a known correlation between such in

vitro results and in vivo activity, may be sufficient to establish practical utility". Such a correlation does not exist in the art of cancer therapy employing CDK2 inhibitors.

In a peripheral issue involving assaying insulin-like growth factor-I ("IGF- I") in Genentech Inc. v. Chiron Corp. 55 USPQ2d 1636, U.S. Court of Appeals Federal Circuit wrote "by the critical date, ... [s]pecific binding in an RRA was known by those skilled in the art to be reasonably correlated with the in vivo biological activity of IGF-I."

In Ex parte Bhide 42 USPQ2d 1441, the Board of Patent Appeals and Interferences wrote "While in vitro or in vivo tests would not be the only possible way to overcome our basis for questioning applicants' utility, in vitro or in vivo tests certainly would provide relevant evidence". The issue in the present case is not the utility of applicants' compounds, which was at issue in Ex parte Bhide 42 USPQ2d 1441, but rather the narrower issue of enablement for claims drawn to the treatment of all cancers. Since such a claim is inherently not credible, the standard of proof required for such an assertion must be high.

In a case concerning a DNA sequence encoding a mature human IL-3 protein, Ex parte Anderson 30 USPQ2d 1866, the Board of Patent Appeals and Interferences wrote in passing "We question whether one skilled in the art would accept appellants' in vitro test as predictive of in vivo results and whether one skilled in the art would know how to use the Pro (8) protein made .... Should the claims of this application be prosecuted further in a continuing application we urge the examiner to consider the enablement and utility aspects of patentability" In an anti-tumor application, Ex parte Aggarwal 23 USPQ2d 1334, the Board of Patent Appeals and Interferences wrote

"there is considerable doubt that those skilled in the art would be willing to accept appellants' in vitro tests and in vivo tests as established models predictive of utility against tumors in humans. See In re Jolles, 628 F.2d 1322, 206 USPQ 885 The examiner had more than adequate reason to doubt the objective truth of the broad statement of utility set forth in appellants' specification." In the most definitive finding on this issue of the adequacy of in vitro assays for clinical claims, Ex parte Stevens 16 USPQ2d 1379 the Board of Patent Appeals and Interferences wrote "The examiner's position is based on the supposition that the facts described above evidence a prima facie case of nonenablement with regard to the disclosed utility in light of all the applicable legal precedents. Where as here, the disclosed utility is the treatment of cancer, we agree with this supposition. The examiner has cited Ex parte Busse, 1 USPQ2d 1908. In that case, the Board of Patent Appeals and Interferences reviewed the relevant prior decisions of its reviewing court. We shall not repeat those citations here. Suffice it to say that in every cited case the narrow issue involved was whether or not the evidence of record was based on in vivo or in vitro studies which were generally recognized by those of ordinary skill in the art as being reasonably predictive of success in the practical utility under consideration, i.e., human or, at least, mammalian therapy."

In a vaccine case, Ex parte Maas 14 USPQ2d 1762, the Board of Patent Appeals and Interferences wrote "First, although appellants' specification describes certain in vitro experiments, there is no correlation on this record between in vitro experiments and a practical utility in currently available form for humans or animals. It is not enough to rely on in vitro studies where, as here, a person having ordinary skill in the art has no

basis for perceiving those studies as constituting recognized screening procedures with clear relevance to utility in humans or animals. The burden is on appellants to establish the significance of the in vitro experiments set forth in their specification."

Specification does not enable any physician skilled in the art of medicine, to use the compound of the invention commensurate in scope with the claims. Applicants have not asserted that it is art recognized that the assays are correlated to clinical efficacy for treatment of all indication mediated by any kinase. There is no working example of treatment of any disease in man or animal. The state of the clinical arts in does not provide any agent which effective against all cancers. Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of in vivo efficacy by those skilled in the art. See for example In re Ruskin 148 USPQ 221; Exparte Jovanovics 211 USPQ 907.

Based on the fact situation of the instant application, In re Buting, 163 USPQ 689 (CCPA 1969) (cited in the previous office actions) is on point and more applicable to the instant claims wherein 'evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers. The judges in that case indicated that "We are not aware of any reputable authority which would accept appellant's two clinical cases as establishing utility for treatment of cancer in humans. As was pointed out in Brenner v. Manson, 148 USPQ 689, a process to be patentable must produce a useful result and be of substantial utility not merely of scientific interest or for further testing. In this case further testing seems necessary".

In summary, applicants have not provided any evidence of record that the instantly claimed compounds can effectively be used in the treatment of all cancers in hypoxic environment in general and therefore, it is maintained that one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Allowable Subject Matter

Claims 27 and 36 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is

James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624